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HOUSTON, TX 77056				
EXAMINER				
ARNOLD, ERNST V				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/563,278

Applicant(s)

ABRAINI ET AL.

Examiner

ERNST V. ARNOLD

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO-893)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date 10/6/06

DETAILED ACTION

Claims 1-15 have been canceled. Claims 16-30 are pending and under examination.

Comment: Please insert the 371 continuity data at the top of page 1 of the specification.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Foreign references on the information disclosure statement filed on 10/06/06 have been considered to the extent of their English language equivalent.

Specification

Content of Specification

Applicant is reminded about the proper sections to the specification. There is no brief description of the drawings. Please correct.

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

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- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).
- (e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the

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invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (l) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Claim Rejections - 35 U.S.C. §§ 101 and 112, Second Paragraph

The following are quotations of 35 U.S.C. §§ 101 and 112, second paragraph, respectively, which form the basis of the claim rejections as set forth under this particular section of the Official Action:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-25 are rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. See, *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967). In addition, claims 16-25 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, a claim is rendered indefinite when said claim merely recites a use without any active, positive steps delimiting how this use is actually practiced. See MPEP 2175.03(q). As a result, the Applicants are respectfully required to redraft the aforementioned use claims as statutory process claims that delimit active, positive steps on how to use a composition according to the invention as originally filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 30 recites the broad recitation 10% to 20 by volume of xenon and from 45% to 50% of nitrous oxide, and the claim also recites xenon is about 16% and nitrous oxide is about 50% which is the narrower statement of the range/limitation. The claim will be interpreted as it reads on the broad recitation range.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 26, 27, 29 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by

Homi et al. (Anesthesiology 2003, 99,876-881).

Homi et al. provide gaseous compositions and methods of administering the gas to a subject (See: Materials and Methods page 876). Homi et al. administered three gas mixtures to mice subjected to 60 minutes of middle cerebral artery occlusion: 1) 70% xenon and 30% oxygen; 2) 70% nitrous oxide and 30% oxygen; and 3) 35% xenon and 35% nitrous oxide and 30% oxygen (Page 877, left column, last paragraph; page 878, under results; Table 2, page 878 upper right and corner and Figure 1, page 879, for example). It is the Examiner's position that 35% is "about 30%" of instant claim 29.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mondain-Monval (US 4,820,258).

Mondain-Monval disclose gaseous mixtures containing from about 50 to 80% by volume nitrous oxide; at least about 20% by volume oxygen and an inert gas; xenon (Claims 1-5). Thus the disclosure of Mondain-Monval embraces a gaseous mixture of 50% by volume nitrous oxide; 20% by volume oxygen and 30 % by volume xenon or 50% nitrous oxide; 30% oxygen and 20% xenon thus anticipating instant claims 26, 27 and 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelt et al. (WO 00/53192) in view of David et al. (reference C3 on the IDS submitted on 10/06/06) and Jevtovic-Todorovic et al. (reference C7 on the IDS submitted on 10/06/06) and Homi et al. (Anesthesiology 2003, 99,876-881).

Applicant claims a gaseous mixture containing xenon, nitrous oxide and oxygen.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Homi et al. is described in detail above and that discussion is hereby incorporated by reference.

Petzelt et al. teaches preparation of gaseous mixtures of xenon with 5 to 90% by volume xenon and further contains oxygen and/or nitrogen and/or air (Claims 12-15). Petzelt et al. suggest mixing xenon with other gases harmless for humans (page 6, middle of page). Petzelt et al. teach the use of the gas mixture for treating apoplexy (stroke) and craniocerebral trauma (claims 1, 4 and 8).

David et al. teach and suggest combining xenon and nitrous oxide to obtain optimal subcortical neuroprotection while minimizing the risk of adverse side effects and that the combination could be used in other brain diseases (page 1172, last paragraph). David et al. suggest xenon at approximately 40 vol% as practical therapy for the treatment of stroke in humans (page 1172, middle paragraph).

Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic action of N-methyl-D-aspartate (Right column, page 460). Jevtovic-Todorovic et al. treated adult rats with various gas mixtures of nitrous oxide and oxygen ranging from 20%, 40%, 80%, 150% and 180% nitrous oxide, for example (Page 462, top left column and page 463, methods). Jevtovic-Todorovic et al. suggest that administration of nitrous oxide may provide neuroprotection against cerebral ischemic events that sometimes accompany surgery (Page 463, left column).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Petzelt et al. is that Petzelt et al. do not expressly teach a composition with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%. This deficiency in Petzelt et al. is cured by the teachings of Homi et al., Jevtovic-Todorovic et al. and David et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Petzelt et al. with with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%, as suggested by Homi et al., Jevtovic-Todorovic et al. and David et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Petzelt et al. suggest mixtures with other gases; 2) the art teaches the use of nitrous oxide for the same purpose as xenon in the reference of Petzelt et al. and 3) the art suggests combining nitrous oxide and xenon (See David et al.) and 4) it is merely routine optimization of the ingredients (xenon, nitrous oxide and oxygen) to arrive at the instantly claimed composition. In the absence of evidence to the contrary, the 35% by volume xenon taught by Homi et al. renders obvious 32% by volume xenon in instant claim 28.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelt et al. (WO 00/53192) in view of Jevtovic-Todorovic et al. (reference C7 on the IDS submitted on 10/06/06).

Applicant claims a gaseous mixture containing xenon, nitrous oxide and oxygen.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Petzelt et al. teaches preparation of gaseous mixtures of xenon with 5 to 90% by volume xenon and further contains oxygen and/or nitrogen and/or air (Claims 12-15). Petzelt et al. suggest mixing xenon with other gases harmless for humans (page 6, middle of page). Petzelt et al. teach the use of the gas mixture for treating apoplexy (stroke) and craniocerebral trauma (claims 1, 4 and 8). Petzelt et al. teach treating neurointoxications and thus, Petzelt et al. is directed to protect neurons from neurotoxicity (page 1, first two paragraphs and claims 1-10, for example).

Jevtovic-Todorovic et al. teach a study designed to test the ability of nitrous oxide to protect neurons against excitotoxic action of N-methyl-D-aspartate (Right column, page 460). Jevtovic-Todorovic et al. treated adult rats with various gas mixtures of nitrous oxide and oxygen ranging from 20%, 40%, 80%, 150% and 180% nitrous oxide, for example (Page 462, top left column and page 463, methods). Jevtovic-Todorovic et al. suggest that administration of nitrous oxide may provide neuroprotection against cerebral ischemic events that sometimes accompany surgery (Page 463, left column).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Petzelt et al. is that Petzelt et al. do not expressly teach a composition with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%. This deficiency in Petzelt et al. is cured by the teachings of Jevtovic-Todorovic et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Petzelt et al. with with 20-40% nitrous oxide or a composition of xenon and nitrous oxide of about 30%, as suggested by Jevtovic-Todorovic et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because: 1) Petzelt et al. suggest mixtures with other gases; 2) the art teaches the use of nitrous oxide for the same purpose as xenon in the reference of Petzelt et al. and 3) it is merely routine optimization of the ingredients (xenon, nitrous oxide and oxygen) to arrive at the instantly claimed composition.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

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Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Please note that there is a potential double patenting rejection of claims 1-15, once they are amended to a proper statutory class of invention, over the method claims in copending application 10/758,513 which has been allowed on 4/4/08.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ernst V Arnold/
Examiner, Art Unit 1616
Technology Center 1600